K050948

MAY 1 8 2005

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

BAUSCH & LOMB® PureVision™ Multi-Focal (balafilcon A) Visibility Tinted Contact Lens

1. Submitter Information:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Anne Zavertnik
Manager, Regulatory Affairs
Telephone No.: (585) 338-5816

2. Device Identification:

Common Name: Soft (hydrophilic) contact lens

Proprietary Name: BAUSCH & LOMB® PureVision™ Multi-Focal (balafilcon A) Visibility Tinted Contact Lens

Classification Name: Daily Wear, Soft (hydrophilic) Contact Lens

Device Classification: Class II, 21 CFR 886.5925

3. Description of Device:

The PureVision Multi-Focal Contact Lens is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. The lens material is the same silicone-hydrogel material as the visibility tinted balafilcon A contact lens described in K972454 and P980006. The color additive conforms with 21 CFR Part 73.3106.

Parameter Ranges	Specification
Diameter:	13.5 to 15.5 mm
Base Curve Range:	7.5 to 9.5 mm
Center Thickness:	varies with power, 0.05 to 0.50mm
Powers:	+20.00D to -20.00D
Add Powers:	+0.75 to +5.00D

4. Indications for Use:

BAUSCH & LOMB® PureVision™ Multi-Focal (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters with add power ranging from +0.75D to +5.00D.

Replacement schedules may vary from patient to patient, and should be decided by eye care practitioners in consultation with their patients. The lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professional. The lens may be disinfected using a chemical disinfection system.

FREQUENT/PLANNED REPLACEMENT WEAR

When prescribed for Frequent/Planned Replacement Wear, the PureVision™ Multi-Focal Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professional. The lens may be disinfected using a chemical disinfection system.

DISPOSABLE WEAR

When prescribed for Disposable Wear, the PureVision™ Multi-Focal Contact Lens is to be discarded after each removal.

5. Predicate Devices:

The predicate devices were selected to address material type, lens design and indications for use.

Lens material:
Bausch & Lomb® PureVision™ (balafilcon A) Visibility Tinted Contact Lens, FDA Group III, low water, ionic contact lens, is marketed under K972454 and P980006.

Lens Design and Indications for use:
Bausch & Lomb® SofLens® Multi-Focal (polymacon) Visibility Tinted Contact Lens is an aspheric lens design and is marketed for daily wear of correction of presbyopia under K020927.

6. Substantial Equivalence:

Material Similarities		
	PureVision™ Multi-Focal Contact Lens (subject device)	PureVision™ Contact Lens
Material	Balafilcon A	Balafilcon A
Water Content	36%	36%
FDA Group	Group III (low water/ionic)	Group III (low water/ionic)
Oxygen Permeability (Dk) †	91* 101**	91* 101**
Color Additive	Reactive Blue Dye 246	Reactive Blue Dye 246
Manufacturing Method	Cast Mold	Cast Mold
Lens Design and Indications Similarities		
	PureVision™ Multi-Focal Contact Lens (subject device)	SofLens® Multi-Focal Contact Lens
Lens Design	Aspheric Multifocal Concentric – Center Near	Aspheric Multifocal Concentric – Center Near
Intended Use	Multifocal - daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia.	Multifocal - daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia.

† Dk Units = $x10^{-11}[cm^3O_2(STP)xcm]/(secxcm^2xmm\ Hg)@35^oC$ (Polarographic Method)
*Boundary and Edge Corrected ** Boundary and Non-Edge Corrected

By reference, data from the series of non-clinical laboratory tests and clinical studies previously performed to assess the safety and effectiveness of the balafilcon A contact lens can be found in K944895, cleared December 19, 1994 and K972454, cleared August 8, 1997.

Conclusion

The PureVision Multi-Focal Contact Lens is substantially equivalent to predicate devices currently legally marketed for the lens material, design and intended uses. The risks and benefits of the PureVision Multi-Focal Contact Lens are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2005

Bausch & Lomb, Inc.
c/o Ms. Ann Zavertnik
1400 North Goodman St.
Rochester, NY 14609

Re: K050948
Trade/Device Name: Baush & Lomb® PureVision™ Multi-Focal (balafilcon A) Visibility Tinted Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: April 13, 2005
Received: April 18, 2005

Dear Ms. Ann Zavertnik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Indications for Use Statement

510(k) Number (if known): K050948

Device Name: BAUSCH & LOMB® PureVision™ Multi-Focal (balafilcon A) Visibility Tinted Contact Lens

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DISPOSABLE WEAR

When prescribed for Disposable Wear, the PureVision™ Multi-Focal Contact Lens is to be discarded after each removal.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K050948